K073075

# 510(k) SUMMARY

MAR 31 2008

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: October 29, 2007

TRADE OR PROPRIETARY NAME: FRIADENT Implant Systems/Indication

CLASSIFICATION NAME: Endosseous dental implant (21 CFR 872.3640)

PREDICATE DEVICES: Various Brånemark System Implants (K022562)
Astra Tech Implants – Dental System (K041492)

DEVICE DESCRIPTION: The FRIADENT Implant Systems consist of root-formed threaded screws made from commercially pure titanium and coated with FRIADENT plus surface.

The indication for use of the FRIADENT Implant Systems includes the immediate loading applications on single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or II bone).

INTENDED USE: The FRIADENT Implant systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System) are for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The FRIADENT Implant Systems are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in this submission have been used in legally marketed devices. No changes have been made to these implant systems. This submission expands the indications for use. Therefore, it was determined that no additional biocompatibility testing was necessary.

We believe that the performance data provided and the research and development and marketing history of the unchanged device support the safety and effectiveness of the FRIADENT Implant Systems for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2008

Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K073075
Trade/Device Name: FRIADENT Implant Systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: February 28, 2008
Received: February 29, 2008

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073075

# INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: FRIADENT Implant Systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System)

Indications for Use:

The FRIADENT Implant systems (FRIALIT® plus Dental Implant System, XiVE® S plus Dental Implant System, XiVE® TG plus Dental Implant System, ANKYLOS® plus Dental Implant System) are for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The FRIADENT Implant Systems are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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